K021845

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact

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Classification Reference 21 CFR 868.2375

Product Code MNR – Ventilatory Effort Recorder

Proprietary Name Respironics Stardust II

Predicate Device(s) Respironics Stardust (K973920)

Respironics REMstar Auto (K012554/K031460)

Reason for submission Modified design/intended use.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Respironics Stardust II as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 1998.

Intended Use

The Stardust II is indicated for use by Health Care Professionals to aid in the diagnosis of sleep-related breathing disorders in adult patients weighing more than 30kg in the home, hospital or other clinical setting.

The Stardust II is intended for use during sleep disorder studies to detect up to 5 physiological signals: percent SpO2 (functional), pulse rate, oral/nasal airflow, respiratory effort and body position (i.e., supine or non-supine).

Device Description

The Respironics Stardust II records physiological signals acquired during sleep and uses proprietary algorithms to determine and report the following respiratory waveforms and events:
Airflow*
Effort
SpO2
Pulse rate
Apnea
Hypopnea
Desaturation

*Nasal airflow can be acquired with a pressure cannula or thermistor sensor.

The Stardust II can also interface with various Respironics pressure therapy devices to report available device/patient information (i.e., event flags and real time streamed data). When used with these devices, the Stardust II is not intended to be a diagnostic application, but rather a portable recorder to assess the quality of the at home titration of an auto-titrating device and determine if there are still events occurring and to assess the therapeutic benefit of the already diagnosed OSA patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2004

Ms. Zita A. Yurko
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1001 Murry Ridge Lane
Murrysville, PA 15668

Re: K021845
Trade Name: Stardust II
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: II
Product Code: MNR
Dated: May 4, 2004
Received: May 5, 2004

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

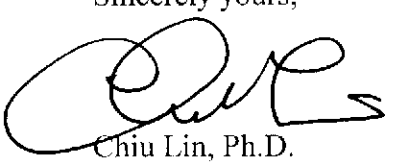
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



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Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
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Radiological Health

Enclosure

510(k) Number (if known): K021845

Device Name: Respironics Stardust II

Intended Use/Indications for Use

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The Stardust II is intended for use during sleep disorder studies to detect up to 5 physiological signals: percent SpO2 (functional), pulse rate, oral/nasal airflow, respiratory effort and body position (i.e., supine or non-supine).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use XXX OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K021845